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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/787,026	02/25/2004	Ioannis Pallikaris	10781/26	3908

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BRINKS HOFER GILSON & LIONE
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CHICAGO, IL 60610

EXAMINER

NGUYEN, VI X

ART UNIT	PAPER NUMBER
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3731

MAIL DATE	DELIVERY MODE
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07/02/2010

PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No. 10/787,026	Applicant(s) PALLIKARIS ET AL.	
	Examiner VICTOR X. NGUYEN	Art Unit 3731	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 08 April 2009.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 26-33 is/are pending in the application.
- 4a) Of the above claim(s) _____ is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 26-33 is/are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☒ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____ |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>See Continuation Sheet</u> . | 6) <input type="checkbox"/> Other: _____ |

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :3/24/08,5/28/08, 6/5/08, 9/8/09, 5/5/10.

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DETAILED ACTION

Claim Rejections - 35 USC § 112

1. In response to applicant's remarks of 4/8/2009, the examiner has withdrawn the Specification objection and all prior 35 USC 112- first rejections.

Double Patenting

2. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970); and, *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

Claims 26 and 33 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1, 41, 154, 158, 164, 166 of U.S. Patent No.7,004,953. Although the conflicting claims are not identical, they are not patentably distinct from each other because they recite the same subject matters as following: placing an epithelial delaminator or an electro-mechanical device for separating the epithelial layer or to lift the epithelium layer.

Information Disclosure Statement

3. The information disclosure statement (IDS) submitted on 3/24/2008, 5/28/2008, 6/5/2008, 9/8/2009, 5/5/2010 are acknowledged. The submission is in compliance with the

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provisions of 37 CFR 1.97. Accordingly, the examiner is considering the information disclosure statement(s).

Specification

4. The disclosure is objected to because of the following informalities: The first paragraph of the specification should be updated to reflect that US application 10/098,167 is now issued US patent 7,004,953 and US application 09/911,356 is now issued US patent 7,156,859.

Claim Objections

5. Claim 26 is objected to because of the following informalities: Claim 26: “an epithelial delaminator” in line 3 should be “an epithelial delaminator member”. Appropriate correction is required.

Claim Rejections - 35 USC § 102

6. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

Claims 26, 33 are rejected under 35 U.S.C. 102(b) as being anticipated by Zelman US 5,571,124.

Claim 26: Zelman discloses a method for lifting epithelium from an eye 10 having a cornea 12 with an epithelium 14 and stroma (see col. 6, lines 12-13), comprising the steps of: placing an epithelial delaminator member (the combination of upper surface 50, lower surface 52 and a blunt leading edge 59, fig. 9) and moving the epithelium delaminator member to apply a mechanical force beneath the epithelium with a force sufficient to lift the epithelium in a

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continuous layer but not to cut the stroma (it is noted that the edge 59 of distal end 58 is dull or blunt which is incapable of cutting the stroma, see col. 9, lines 46-47, col. 11, lines 33-38).

Claim33: Zelman discloses the lifted epithelium contains substantially no corneal tissue (it is noted that the edge 59 of distal end 58 is dull or blunt which is incapable of cutting the stroma, see col. 9, lines 46-47, col. 11, lines 33-38).

Claim Rejections - 35 USC § 103

7. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

Claims 27-28 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zema in view of Roberts et al US 2003/0208190.

Claim 27: Zema discloses the invention substantially as claimed (see claim 26 above). Zema fails to disclose the step of applying a mechanical force comprises a step of forming an epithelial flap. However, Roberts et al teach a mechanical force comprises a step of forming an epithelial flap (paragraphs 13-15, 111). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method step of Zema with a mechanical force comprises a step of forming an epithelial flap as taught by Roberts in order to reduce corneal epithelial abrasions and further help to expedite the visual acuity by facilitating formation of a flap that is not wrinkled and fits well upon replacement following the Lasik procedure.

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Claim 28: Zema discloses the invention substantially as claimed (see claim 26 above). Zema fails to disclose the step of applying a mechanical force comprises a step of peeling the epithelial flap to expose the stroma. However, Roberts et al teach a mechanical force comprises a step of peeling the epithelial flap to expose the stroma (paragraphs 13-15, 111, and Roberts claims 4, 10, 20). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method step of Zema with a mechanical force comprises a step of peeling the epithelial flap to expose the stroma as taught by Roberts in order to reduce corneal epithelial abrasions and further help to expedite the visual acuity by facilitating formation of a flap that is not wrinkled and fits well upon replacement following the Lasik procedure.

Claims 29-32 are rejected under 35 U.S.C. 103(a) as being unpatentable over Zema in view of Johnson US 5,603,709.

Claims 29-31: Zema discloses the invention substantially as claimed (see claim 26 above). Zema fails to disclose the step of reshaping the stroma comprises applying a laser beam to the stroma. However, Johnson teaches the step of reshaping the stroma 54 comprises applying a laser beam 42 to the stroma (figures 1, 2, see col. 1, lines 55-67, col. 5, lines 13-42). Therefore, it would have been obvious to one having ordinary skill in the art at the time the invention was made to modify the method step of Zema with the step of reshaping the stroma comprises applying a laser beam to the stroma as taught by Johnson in order to reshape the cornea to improve sight. As to claim 32, Johnson teaches the step of replacing the flap on the stroma as best seen in figures 1, 2, see col. 1, lines 55-67, col. 5, lines 13-42.

Conclusion

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Any inquiry concerning this communication or earlier communications from the examiner should be directed to VICTOR X. NGUYEN whose telephone number is (571)272-4699. The examiner can normally be reached on M-F (8-4.30 P.M).

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Anhtuan Nguyen can be reached on (571) 272-4963. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

/Victor X Nguyen/
Examiner, Art Unit 3731